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DADE BEHRING

December 2, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: FDA Docket No. 2001D-0044: Draft Guidance for Industry and FDA Staff, Clinical Laboratory Improvement Amendments of 1988 Waiver Applications

Dade Behring Inc., a manufacturer of in vitro diagnostic devices, respectfully submits comments on the Draft Guidance: Clinical Laboratory Improvement Amendments of 1988 Waiver Applications. The availability of the guidance document was announced in the Federal Register Vol. 70, No. 172, September 7, 2005.

Dade Behring is pleased that FDA has developed this guidance which provides medical device manufacturers with more specific criteria for determining when a device is suitable for CLIA waiver and clear expectations for labeling of the device. The increased emphasis on the studies expected to support a petition for waiver and descriptions for handling reference methods will ensure greater consistency in supporting data provided to the agency and we believe will also improve consistency of waiver decisions.

In the introduction to the guidance it is stated that the studies described therein are recommended for inclusion in a waiver application. Our interpretation is that the specific criteria listed are examples of acceptable means for demonstration of the required attributes. For example section IV,B ,3- Performance Criteria for WM with Quantitative Results indicates the use of several tools to determine quantitative results (i.e. Allowable Total Error, Limits for Erroneous Results, Clarke error Grid, etc). We believe that FDA's intent is to allow alternate approaches. We support this flexibility which accommodates inherent differences in device types, but would like to see that flexibility further emphasized in the body of the guidance. For example, a statement in the introductory paragraph of section IV, B, 3 indicating that the parameters listed are one means of establishing suitable criteria but that other parameters may be used if they satisfy statutory requirements, would further clarify FDA's expectations.

We appreciate this opportunity to provide comments and hope that the agency will find them of value. We look forward to issuance of these guidelines in their final form. If Dade Behring can be of assistance with additional questions please feel free to contact me.

Sincerely,

Robin Norris
Vice President, RA/QS

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